



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/750,270

01/02/2004

Marvin A. Genshaw

MSE #2672

1737

7590

12/20/2005

Elizabeth A. Levy, Esq.  
Bayer Healthcare LLC  
P.O. Box 40  
Elkhart, IN 46515-0040

EXAMINER

SUAREZ, FELIX E

ART UNIT

PAPER NUMBER

2857

DATE MAILED: 12/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/750,270	GENSHAW, MARVIN A.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Felix E. Suarez	2857	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 11-39 and 41-46 is/are rejected.
- 7) ☒ Claim(s) 7-10 and 40 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-6, 11-30 and 41-46 rejected under 35 U.S.C. 102(b) as being unpatentable over Charlton et al. (U.S. Patent No. 5,856,195).

With respect to claims 1 and 39, Charlton et al. (hereafter Charlton) teaches a test device (or system) for determining the concentration of an analyte in a sample, the test device having a memory in which a plurality of calibration adjustments corresponding to a plurality of calibration numbers are stored, the test device being adapted to receive a test sensor for collecting the sample, the test sensor containing a reagent adapted to produce a reaction indicative of the concentration of the analyte in the body fluid, the test sensor having an associated calibration number of a plurality of digits, the device comprising:

a measuring unit for measuring the reaction of the reagent and the analyte and for generating a signal indicative of the measured reaction (see col. 1, lines 15-35; col. 13, lines 31-36 and col. 14, lines 42-44);

a single calibration input element for permitting a user to input the calibration number, one digit at a time, associated with the test sensor (see col. 4, lines 1-18 and col. 5 line 63 to col. 6 line 7);

a processor electronically coupled to the single calibration input element and the measuring unit, the processor being adapted to determine the concentration of the analyte in the sample in response to receiving the inputted calibration number and receiving the signal indicative of the measured reaction from the measuring unit (see col. 4, lines 1-18 and col. 4, lines 42-47); and

a user display electronically coupled to the processor for displaying digits to be selected from by a user inputting the calibration number and for displaying the determined concentration of the analyte in the sample (see col. 3, lines 26-30 and FIG. 1).

With respect to claim 2, Charlton further teaches that, the calibration number includes a first digit and a second digit (see col. 6, lines 26-33), the processor being adapted to commence scrolling through a plurality of numbers on the user display (see col. 4, lines 42-60), from which the first digit of the calibration number is selected, upon activation of the single calibration input element by the user, the processor being adapted to suspend scrolling through the numbers upon deactivation of the single calibration input element by the user, the processor accepting the number displayed on the user display at the time of

the deactivation of the single calibration input element as the first digit of the calibration number (see col. 11, lines 38-62).

With respect to claims 3, 24, 28 and 46, Charlton further teaches that, the processor accepts the displayed number after a predetermined time period measured from the deactivation of the single calibration input element (see col. 3, lines 32-47 and col. 11, lines 51-62).

With respect to claim 4, Charlton further teaches that, the processor is adapted to commence scrolling through a plurality of numbers on the user display, from which the second digit of the calibration number is selected, upon activation of the single calibration input element by the user after acceptance by the processor of the first digit of the calibration number, the processor being adapted to suspend scrolling through the numbers upon deactivation of the single calibration input element by the user, the processor accepting the number displayed on the user display at the time of the deactivation of the single calibration input element as the second digit of the calibration number (see col. 6, lines 26-33 and col. 11, lines 38-62).

With respect to claims 5 and 41, Charlton further teaches that, the processor prompts the user, via the display, to input a first digit of the calibration number (see col. 6, lines 8-18 and col. 11, lines 18-25).

With respect to claim 6, Charlton further teaches that, the processor is adapted to scroll through a plurality of numbers on the user display, from which the first digit of the calibration number is selected, in response to a plurality of activations of the single calibration input element by the user, the processor accepting a displayed number as the first digit of the calibration number after a predetermined time measured from a most-recent activation of the single calibration input element (see col. 4, lines 52-65 and col. 11, lines 38-50).

With respect to claim 11, Charlton further teaches that, the calibration number consists of a predetermined number of digits, the processor adjusting the at least one adjustable parameter of the concentration equation according to the stored adjustment corresponding to the input calibration number upon receipt of each of the predetermined number of digits of the calibration number (see col. 11, lines 51-62).

With respect to claims 12, 25 and 29, Charlton further teaches comprising an enter input element, the processor accepting the inputted calibration number upon receipt user input, via the enter input element, indicating that each of the plurality of digits of the predetermined number have been input (see col. 11, lines 18-37).

With respect to claims 13, 31 and 42, Charlton further teaches that, the calibration number ranges between two digits and five digits (see col. 6, lines 61-63 and col. 8, lines 29-36).

With respect to claims 14, 26, 30, 32 and 43, Charlton further teaches that, the calibration number has a number base selected from the group consisting of number base three, number base four, number base five, and number base six (see col. 9, lines 31-35 and col. 10, lines 31-36).

With respect to claim 15, Charlton further teaches that, the processor is adapted to display on the user display a previously entered calibration number upon an initial activation of the single calibration input element (see col. 3, lines 32-47).

With respect to claims 16 and 33, Charlton further teaches that, the reagent is adapted to produce an optical reaction and the measuring unit is adapted to measure the optical reaction (see col. 4, lines 16-18).

With respect to claims 17 and 34, Charlton further teaches that, the optical reaction is a colorimetric reaction and the measuring unit is adapted to measure the colorimetric reaction (see col. 4, lines 16-18 and col. 1, lines 15-26).

With respect to claims 18 and 35, Charlton further teaches that, the reagent is adapted to produce an electrochemical reaction and the measuring unit is adapted to measure the electrochemical reaction (see col. 4, lines 16-18 and col. 1, lines 15-26).

With respect to claims 19 and 36, Charlton further teaches that, the sample is blood (see col. 4, lines 39-56).

With respect to claims 20 and 37, Charlton further teaches that, the analyte is glucose (see col. 4, lines 39-56).

With respect to claim 22, Charlton teaches a method for entering a multiple-digit calibration number into a test device, the test device having a memory in which a plurality of calibration adjustments corresponding to a plurality of calibration numbers are stored, the test device being adapted to receive a test sensor for collecting a sample, the test sensor containing a reagent adapted to produce a reaction indicative of the concentration of the analyte in the sample, the test sensor having an associated calibration number, the method comprising:

prompting a user, via a user display, to enter a digit of the calibration number (see col. 3, lines 32-47);



receiving input from the user, via a single calibration input element, indicative of the calibration number, one digit at a time (see col. 4, lines 1-18 and col. 5 line 63 to col. 6 line 7);

measuring the reaction of between an analyte in a collected body fluid sample and the reagent contained in the test sensor (see col. 4, lines 44-56);

determining the concentration of the analyte in the body fluid in response to receiving the calibration number from the user and measuring the reaction (see col. 13. lines 31-36 and col. 1, lines 10-35); and

displaying the determined concentration of the analyte in the body fluid on the user display (see col. 3, lines 32-47 and col. 4, lines 52-60).

With respect to claims 23 and 27, Charlton further that, receiving input from the user indicative of the calibration number further comprises:

(a) prompting the user to input a particular one of the multiple digits of the calibration number (see col. 4, lines 52-60) ;

(b) scrolling through a plurality of digits, one at a time, from which the particular one of the multiple digits can be selected, on the user display in response to repeated activations of the single calibration input element by the user until a displayed number is displayed on the user display (see col. 6, lines 22-33);

(c) accepting the displayed number as the particular one of the multiple-digits of the calibration number (see col. 6, lines 46-48); and

(d) repeating (a) through (c) until all of the digits of the multiple-digit calibration number have been accepted (see col. 4, lines 56-59).

With respect to claim 38, Charlton further teaches that, determining comprises determining the concentration of the analyte in the sample according to a calibration equation having an adjustable parameter and adjusting the adjustable parameter according to the stored adjustment corresponding to the inputted calibration number (see col. 11, lines 38-62).

With respect to claim 45, Charlton further teaches that, the processor is adapted to display on the user display a previously entered calibration number upon an initial activation of the single calibration input element (see col. 3, lines 32-47 and col. 11, lines 18-25).

***Allowable Subject Matter***

2. Claims 7-10 and 40, are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

3. The following is a statement of reasons for the indication of allowable subject matter:

Claims 7-10, would be allowable over the prior art for at least the reason that the prior art fail to teach or suggest that:

the processor prompts the user, via the display, to input a second digit of the calibration number upon acceptance of the first digit.

Claim 40 would be allowable over the prior art for at least the reason that the prior art fail to teach or suggest that:

the processor is adapted to receive a calibration number of a specific number of digits, the processor permitting a user to scroll through an array of numbers being displayed on the user display, one number at a time, such that the next number in the array of numbers to be displayed is displayed in response to each activation of the single calibration input element, each digit of the calibration number being selected from the array of numbers, the processor accepting a displayed number as the particular digit of the calibration number presently being inputted by the user in response to not receiving input from the single calibration input element for a predetermined time period, the processor entering the accepted numbers as the calibration number upon acceptance of a number as a last number of the specific number of digits.

### ***Final Rejection***

#### ***Response to Arguments***

4. This action is responsive to papers filed 09/02/2005.
5. Applicant's arguments filed 09/02/2005 have been fully considered but they are not persuasive respect to independent claims 1, 22 and 39. The

Examiner has thoroughly reviewed applicant arguments, but believes the cited references to reasonably and properly meet the claimed limitations.

Applicants' primary argument is that Charlton et al. [U.S. Patent No. 5,856,195] (hereafter Charlton) do not teach, disclose, or suggest, the features in independent claims 1, 22 and 39, and that Charlton does not disclose or suggest that, *"Independent claims 1, 22 and 39, on the other hand, have specific limitations discussed above generally associated with a single calibration input element adapted to permit a user to input the calibration number or an act of the user inputting the calibration number via the single calibration input element"*.

But Charlton teaches that:

A Digital calibration encoding can be defined by either direct encoding through printing or cutting traces with a laser, for a particular sensor lot. An analog system as illustrated and described with respect to FIGS. 7A, 7B, 7C and 7D can be used that is based on measuring resistors that are selectively located at predefined positions, for example, represented by lines 152 and connected to the selected contacts O, I, J as shown in FIG. 7B. In the analog label 170 or 170A, resistors at lines 152, or R1 and R2, preferably are of the thick film type applied to the label by standard screen printing technology (see col. 5 line 63 to col. 6 line 7).

Charlton also teaches that, FIG. 6B illustrates an exemplary trace pattern for calibration encoded label 70. As shown in FIG. 6B, autocalibration label 70 includes three sets of contact connections, first contacts 72, TO, A, D and E connected to the outer ring or path 76 representing a logical 1, second contacts 72, TI, B, C, F connected

Art Unit: 2857

to the inner ring or path 74 representing a logical 0; and third null contacts or no connection representing the home position or sync (see col. 6, lines 26-33).

Charlton further teaches that, the arrow 80 is a visual aid to help the user orientate the package 50 containing the label 70 in the instrument (see col. 6, lines 45-48).

The Examiner considers that, the Analog system illustrated in FIG. 6B can be used as an exemplary trace pattern for an autocalibration encoded label and this autocalibration encoded label, includes three sets of contact connections with the user.

The Examiner considers that the device shown in FIG. 6 allows to a user to input a calibration number (see FIG. 7C) through a calibration input element, the calibration input elements in FIG. 6B, are TO, A, D and E on the outer ring or pat and TI, B, C, F on the inner ring.

The Examiner considers that the Charlton system is capable to select a number calibration through a input element and that, the Charlton system also helps to the user orientate the package containing the calibration with a visual arrow printed on the device, as show in the FIG. 6B.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory

period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### ***Conclusion***

#### ***Prior Art***

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Douglas et al. [U.S. Patent No. 6,106,780] describes an intelligent calibration device.

Douglas et al. [U.S. Patent No. 6,750,962] describes an optics alignment and calibration system.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Felix Suarez, whose telephone number is (571) 272-2223. The examiner can normally be reached on weekdays from 8:30 a.m. to 5:00 p.m.

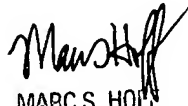
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marc Hoff can be reached on (571) 272-2216. The fax phone

Art Unit: 2857

numbers for the organization where this application or proceeding is assigned is  
703-872-9306 for regular communications and for After Final communications.

December 09, 2005

F.S.

  
MARC S. HOFF  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 2800